REMARKS

In the Office Action dated **May 23, 2005**, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following eight separate and distinct inventions:

Group I. Claims 1, 3, 18-20, 22-23, and 5-9 in part, drawn to a method for detecting a cell to the development of an aberrant cell from a subject comprising contacting the cells with immunointeractive molecule specific to LM04 and screening for the level of the complex formation, classified in class 435, subclass 7.1.

Group II. Claims 2, 4, 24-29, and 5-9 in part, drawn to a method for detecting or monitoring a aberrant cells by screening the level of LM04 transcription, classified in class 435, subclass 6.

Group III. Claims 10-17, drawn to immunointeractive molecule and its derivative comprising antibody, which interacts with LM04 or LM04, classified in class 530, subclass 387.1.

Group IV. Claim 21, drawn to a method for detecting a neoplastic cells in a patient comprising introducing a patient with antibody labeled with a reporter molecule and identified the location of the antibody, classified in 424, subclass 9.1.

Group V. Claims 30 and 32-36 in part, drawn to a method of modulating LM04 regulated cellular proliferation by contacting a cell with an agent to modulate LM04 expression or functional activity, classified in class 435, subclass 4.

Group VI. Claim 31 and 32-36 in part, drawn to a method of in vivo treatment and/or prophylaxis of inappropriate LM04 – regulated proliferative cellular activity by administering an agent for to modulate LM04 expression or functional activity, classified in class 424, unsubclassified.

Group VII. Claim 37, drawn to a method for detecting an agent capable of modulating LM04 expression or functional activity, classified in class 435, subclass 4.

Group VIII. Claims 38-39, drawn to a composition comprising a modulating agent identified in claim 37, unclassified.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group I, Claims 1, 3, 18-20, 22-23, and 5-9 in part, drawn to a method for detecting a cell in the development of an aberrant cell from a subject comprising contacting the cells with an immunointeractive molecule specific to LM04 and screening for the level of the complex formation. Applicants also provisionally elect the species of mammary cell from subgroup (a) and hybridoma 16H2 from subgroup (b) for continued prosecution. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

The Examiner acknowledges that Groups I and III are related as product and process of use. However, the Examiner contends that these groups are distinct inventions since the Examiner alleges that the immunointeractive molecule of the Group III can be administered to a

patient for treating a disease rather than being used for the process of Group I drawn to detecting LM04 in a sample from a patient.

The Examiner alleges that Groups III and VIII are distinct inventions on the ground that the immunointeractive molecules of Group III comprise an antibody whereas the modulating agent of Group VIII could be any biologically functional molecule capable of modulating LM04 expression.

The Examiner further alleges that Groups I, II, IV, V, VI and VII are unrelated. The Examiner alleges that detecting LM04 by an immunointeractive molecule of Group I requires an antibody, whereas screening the level of LM04 transcript of Group II requires nucleotides. The Examiner alleges that methods of Groups I and II have different objectives and different modes of operation. The Examiner also alleges that in vivo detection of neoplastic cells of Group IV and in vivo treating of proliferative disorders of Group VI have a different objective, require different materials and have different effects. The Examiner further alleges that modulating LM04 expression of Group IV is an in vitro method for treating the cells with an agent, which has a different objective and uses different materials. The Examiner further alleges that Group VII is a method for screening of an agent capable of modulating LM04 expression, which requires different materials and have different modes of operation. The Examiner is of the opinion that the searches of the proteins described in the present invention are not co-extensive.

In the first instance, Applicants respectfully submit that the present invention is based on a recognition that LM04 plays an important role in mammary development and in breast cancer oncogenesis. Applicants submit that Groups I-VIII are merely different aspect of a single invention disclosed by the present application and are interdependent and related.

Applicants respectfully submit that Groups I and II are related as different aspects for diagnosing an aberrant cell based on upregulation of LM04 expression by detecting LM04 via antibody and monitoring LM04 transcription, respectively.

Applicants submit that Groups I, III and IV are related and employ the same inventive concept. Group I employs the immunointeractive molecule of Groups III and IV. Groups III and IV are also related. The antibody of Group IV is an antibody of Group III labeled by a reporter molecule.

Applicants further submit that Groups V-VIII employ the concept of Groups I and II and are interrelated and interdependent. For example, the purpose of Group V is to modulate the aberrant cell having upregulated LM04 expression detected by the methods of Group I or II.

Applicants submit that, although the methods of Groups I, II, IV, V, VI and VII allegedly employ different materials, these methods are all related to the detection of aberrant cells in Group I or II. Thus, these groups are related to each other and are clearly not independent.

Accordingly, Applicants respectfully submit that Groups I-VIII are merely different aspects of a single invention and are not independent. Particularly, Applicants request that the Examiner should at least consider Groups I, II and IV together.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

The Examiner also states that the inventions have acquired a separate status in the art as evidenced by the separate classification and recognized divergent subject matter and would require independent searches. Thus, the Examiner concludes that restriction for examination purposes is proper.

Reliance on the supposed classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of classes and subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the classes or subclass(es) with which he associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to

change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation

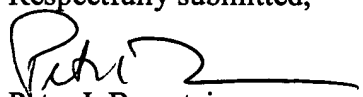
of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined eight groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



Peter I. Bernstein
Registration No. 43,497

SCULLY, SCOTT, MURPHY & PRESSER
400 Garden City Plaza-Ste 300
Garden City, New York 11530
(516) 742-4343
FSD/ZY:ab:bk